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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1138]

Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices--Questions and Answers (Revised); Withdrawal of Guidance

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of the guidance document entitled "Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices--Questions and Answers (Revised)," which was issued in June 2020 (and updated December 2020). FDA is withdrawing this guidance document in recognition that the conditions that created the need for these policies have evolved, such that these policies are no longer needed.

DATES: The withdrawal date is [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2438, Silver Spring, MD 20993-0002, 301-796-5640, Joshua.Nipper@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

As part of FDA's commitment to providing timely guidance to support continuity and response efforts to the Coronavirus Disease 2019 (COVID-19)[1] pandemic, in June 2020, the

[1] The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19).

Agency published this guidance document (June 23, 2020 at 85 FR 34638) and updated it in December 2020, to recognize that the COVID-19 public health emergency was affecting the public health in numerous direct and indirect ways, including device development programs.[2] This guidance document answered frequently asked questions and implemented temporary policies to reduce industry burden.

FDA has continually assessed the needs and circumstances related to these temporary policies, and as relevant needs and circumstances evolved, the Agency made updates and modifications to these temporary policies. FDA has determined that the needs and circumstances related to the temporary policies described in the guidance document have evolved, such that they are no longer needed, and the guidance document should be withdrawn. In weighing the current burden to industry and the Agency relating to the COVID-19 response efforts with the need to ensure patients have timely access to new devices, FDA is withdrawing this guidance document. Below is a brief description of the guidance document and temporary policies that will be withdrawn:

The guidance articulated FDA's policy that for marketing submissions and applications on hold, FDA did not intend to consider a submission or application to be withdrawn for an additional 180 days beyond the relevant response date. Returning to pre-pandemic policies for marketing submissions and applications placed on hold after the withdrawal of this guidance means FDA will generally consider the submission or application to be withdrawn if the submitter or applicant does not provide a complete response to major deficiency letters for Premarket Approval Applications (PMAs) (original and supplements)[3] and Humanitarian Device

[2] The term "device(s)" in this document refers to devices regulated by the Center for Devices and Radiological Health (CDRH) as well as devices regulated by the Center for Biologics Evaluation and Research (CBER), including devices regulated as biological products under section 351 of the Public Health Service (PHS) Act.
[3] For more information, please see the FDA guidance document entitled "FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals).

Exemption (HDE) applications (original and supplements)[4] within 360 days or to additional information letters for 510(k)[5] and De Novo requests[6] within 180 days, consistent with preexisting guidance.

When the COVID-19 public health emergency began, FDA understood that applicants may face challenges affecting their ability to meet their applicable response date for submissions placed on hold. FDA also recognized our potential difficulty in processing a high volume of individual extension requests on a timely basis. To alleviate these concerns, the guidance document articulated that FDA did not intend to consider an application or submission to be withdrawn for an additional 180 days beyond the relevant response date, regardless of whether the applicant submitted an extension request.

By weighing the current burdens on industry with FDA's interest in patients receiving timely access to new devices, FDA has determined it is in the interest of the public health to return to pre-pandemic policies regarding hold times. Reverting to policies regarding hold times described in the preexisting guidance documents should facilitate more timely premarket review of innovative and potentially lifesaving devices. In addition, closing out files that have been abandoned in a timelier manner allows for better management of the device review program. The Agency acknowledges that the circumstances giving rise to the public health emergency declaration for the COVID-19 pandemic continue to exist. However, the conditions that created the need for these policies have evolved, such that these policies are no longer needed, and it is in the best interest of patients and providers to reinstitute the original hold times to ensure

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[4] For more information, please see the FDA guidance document entitled "Humanitarian Device Exemption (HDE) Program" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-device-exemption-hde-program).

[5] For more information, please see the FDA guidance document entitled "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals).

[6] For more information, please see the FDA guidance document entitled "FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals).

patients have timely access to advanced technologies, diagnostics, and therapeutics without unnecessary delay.

The guidance document also discussed FDA's ability to host advisory committee meetings virtually and FDA's intention to work with relevant stakeholders to host all advisory committee meetings virtually. In returning to pre-pandemic policies, FDA will assess the appropriate venue for advisory committee meetings, keeping in mind FDA's successful implementation of virtual advisory committee meetings. Consistent with existing policy, the venue will be announced via the *Federal Register*.

Therefore, after careful review of current Agency processes, industry practices with regard to resolving submission deficiencies, and comments submitted to the public docket associated with the guidance, FDA is withdrawing the "Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices--Questions and Answers (Revised)" guidance in its entirety.

II. Withdrawal Date

The withdrawal date for the guidance document discussed in this document is [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. For submissions or applications that receive a major deficiency letter for PMA and HDE applications or additional information letters for 510(k) and De Novo requests prior to or on the guidance withdrawal date, FDA does not intend to consider the submission or application to be withdrawn for an additional 180 days beyond the relevant response date. For submissions or applications that receive a major deficiency letter or additional information letter after the guidance withdrawal date, FDA will generally consider the application or submission to be withdrawn if a complete response is not received by the relevant response date identified in that letter.

Authority: 21 U.S.C. 371(h)

Dated: June 1, 2022.
Lauren K. Roth,
Associate Commissioner for Policy.

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